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DATE MAILED: 08/29/2008

2474.0010001/BJD/JKM

NOTICE OF ALLOWANCE AND FEE(S) DUE

26111 759n 08/29/2008 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005

10/01/2001

EXAMINER DIBRINO, MARIANNE NMN ARTHMU PAPER NUMBER 1644

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO 8537 Liang Xu

TITLE OF INVENTION: ANTIBODY FRAGMENT-TARGETED IMMUNOLIPOSOMES FOR SYSTEMIC GENE DELIVERY

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	\$0	\$0	\$720	12/01/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown

B. If the status above is to be removed, check box 5b on Part B -Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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appropriate. All further indicated unless corrects maintenance fee notifica	correspondence includir ed below or directed oth	or transmitting the 1880 ig the Patent, advance of herwise in Block 1, by (a	rders and notification of a a) specifying a new corre	maintenance fees w spondence address;	ill be and/or	mailed to the current (b) indicating a sepa	correspondence address a trate "FEE ADDRESS" fo
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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
09/914,046 TITLE OF INVENTION	10/01/2001 : ANTIBODY FRAGMI	ENT-TARGETED IMM	Liang Xu UNOLIPOSOMES FOR S	YSTEMIC GENE I		0010001/BJD/JKM ERY	8537
APPLN, TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE	FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	80	\$0		\$720	12/01/2008
EXAM	IINER	ART UNIT	CLASS-SUBCLASS	1			
DIBRINO, MA	RIANNE NMN	1644	424-141100	J			
"Fee Address" ind PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A	ondence address (or Cha B/122) attached. ication (or "Fee Address 12 or more recent) attach ND RESIDENCE DAT/ less an assignee is ident h in 37 CFR 3.11. Comp	nge of Correspondence Indication form ed. Use of a Customer A TO BE PRINTED ON	2. For printing on the p (1) the names of up to or agents OR, alternati (2) the name of a sing registered attorney or 2 registered patent atte listed, no name will be THE PATENT (print or ty, data will appear on the p T a substitute for filing an (B) RESIDENCE: (CTT)	o 3 registered patent vely, le firm (having as a agent) and the name meys or agents. If r printed. pe) atent. If an assigne assignment.	membes of use name	er a 2p to e is 3	ocument has been filed for
Please check the appropr	iate assignee category or	categories (will not be pr	rinted on the patent):	Individual 🗖 Co	rporati	on or other private gro	oup entity 🗖 Government
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	s SMALL ENTITY state	is. See 37 CFR 1.27.	☐ b. Applicant is no lon				
NOTE: The Issue Fee an interest as shown by the	d Publication Fee (if req records of the United Sta	uired) will not be accepte tes Patent and Trademark	d from anyone other than to Office.	he applicant; a regis	tered a	uttorney or agent; or th	ne assignee or other party in
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This collection of inform an application. Confiden submitting the complete this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	nation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this but 'irginia 22313-1450. DC i13-1450.	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary den, should be sent to the ONOT SEND FEES OR	on is required to obtain or 1.14. This collection is es depending upon the indi- e Chief Information Offic COMPLETED FORMS T	retain a benefit by th timated to take 12 n vidual case. Any cor er, U.S. Patent and O THIS ADDRESS	ie publ ninutes mment Fraden . SENI	ic which is to file (and to complete, including s on the amount of the nark Office, U.S. Depo D TO: Commissioner	by the USPTO to process; g gathering, preparing, and me you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450

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DATE MAILED: 08/29/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
09/914,046	10/01/2001	Liang Xu	2474.0010001/BJD/JKM	8537		
26111 7	26111 7590 08/29/2008			EXAMINER		
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.			DIBRINO, MARIANNE NMN			
1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			ART UNIT PAPER NUM			
			1644			

Determination of Patent Term Extension under 35 U.S.C. 154 (b)

(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Interview Summary

 Application No.
 Applicant(s)

 09/914,046
 XU ET AL.

 Examiner
 Art Unit

 DiBrino Marianne
 1644

,	Examiner	Art Unit	
	DiBrino Marianne	1644	
All participants (applicant, applicant's representative, PTO	personnel):		
(1) <u>DiBrino Marianne</u> .	(3)		
(2) Mills, Jeffrey K.	(4)		
Date of Interview: 29 May 2008.			
Type: a)⊠ Telephonic b)□ Video Conference c)□ Personal [copy given to: 1)□ applicant 2	t)∏ applicant's representative	e]	
Exhibit shown or demonstration conducted: d) Yes If Yes, brief description:	e) No.		
Claim(s) discussed:			
Identification of prior art discussed:			
Agreement with respect to the claims f) ${\color{orange} \boxtimes}$ was reached. ${\color{orange} \ \ g}$)□ was not reached. h)□ N	I/A.	
Substance of Interview including description of the general reached, or any other comments: Mr. Mills gave permission delete "a" and replace it with "the" at part b of claim 1 in the (A fuller description, if necessary, and a copy of the amend allowable, if available, a summary thereof must be attached. Also, where no callowable is available, a summary thereof must be attached.	n for an Examiner's amendments phrase "at a carboxy terminuments which the examiner agopy of the amendments that w	<u>nt to cancel clain</u> i <u>s"</u> . reed would rende	n 73 and to
THE FORMAL WRITTEN REPLY TO THE LAST OFFICE A INTERVIEW. (See MPEP Section 713.04). If a reply to the GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERLE A STATEMENT OF THE SUBSTANCE OF THE INTER requirements on reverse side or on attached sheet.	CTION MUST INCLUDE THE last Office action has alread OF ONE MONTH OR THIRTY ERVIEW SUMMARY FORM,	been filed, APP OAYS FROM T WHICHEVER IS	LICANT IS
	/G.R. Ewoldt/ Primary Examiner, Art Unit 16 Examiner's signature, if requi		

Notice of Allowability

Application No.	Applicant(s)	
09/914,046	XU ET AL.	
Examiner	Art Unit	
DiBrino Marianne	1644	

-- The MALING DATE of this communication appears on the cover sheet with the correspondence address-All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included
herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS
NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative
of the Office or upon publish by the applicant. See 37 CFE1 433 and MERS 1999.

- of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

 1. \(\sum \) This communication is responsive to \(\textit{Applicant's amendment filed 1/25/08}. \)
- The allowed claim(s) is/are 1-4,7,8,12, 69 and 75-80.
- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 - 1. \(\sum \) Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. ____
 - Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

 DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date
- Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413),
- Paper No./Mail Date <u>attached hereto</u>.

 7.

 Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance
- 9. Other _____.

/G.R. Ewoldt/ Primary Examiner. Art Unit 1644

Page 2

Application/Control Number: 09/914,046

Art Unit: 1644

DETAILED ACTION

- 1. Applicant's amendment filed 1/25/08 is acknowledged and has been entered.
- Applicant is reminded of Applicant's election with traverse of Group II, and species of
 immunoliposome comprising a pre-linked antibody fragment that binds a transferrin
 receptor and further comprises DNA encoding wild type p53 in Applicant's responses
 filed 8/27/04 and 4/30/04. Group I had been rejoined to Group II.
- 3. In view of Applicant's amendment of instant claim 1 to delete the recitation of "1:5" and to add in its place the recitation of "1:10" as the lower value in the protein:lipid (w:w) ratio, and in light of Applicant's arguments to the issue of ratio and Fab vs scFv fragments, both presented in Applicant's amendment filed 1/25/08, the prior 103(a) rejections of record are hereby WITHDRAWN.

EXAMINER'S AMENDMENT

4. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's Amendment was given by Mr. Jeffrey K. Mills in a telephone interview on 5/29/08.

- a. In the claims: In claim 1 at line 3 of part "b", the limitation "part of <u>a</u> sulfhydryl group at a carboxy terminus on said antibody fragment" has been changed to ---part of a sulfhydryl group at <u>the</u> carboxy terminus on said antibody fragment [Examiner emphasis].
 - b. Claim 73 has been canceled.

REASONS FOR ALLOWANCE

- 5. The following is an Examiner's statement of reasons for allowance:
 - a. Claims 1-4, 7, 8, 12, 69 and 75-80 are pending and are allowable.
- Applicant's amendment of instant claim 1 and Applicant's arguments in the amendment filed 1/25/08 have resulted in the withdrawal of the prior art rejections of record as enunciated suora.